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OCT 2 5 2000

510(k) Premarket Notification

K002522

SUMMARY OF SAFETY AND EFFECTIVENESS

1. **DEVICE NAME:** Magnetic Resonance Diagnostic Device Accessory
   Model Number: MRT-600
   Trade/Proprietary Name: OPART™

2. **ESTABLISHMENT REGISTRATION:** 2636923

3. **U.S. AGENT NAME AND ADDRESS:** Toshiba America MRI, Inc.
   280 Utah Avenue
   South San Francisco, CA 94080

   CONTACT PERSON: Bruce Clark
   (650)872-2722 ext. 6068

4. **MANUFACTURING SITE:** USA Instruments, Inc.
   1515 Danner Drive
   Aurora, Ohio 44202, USA

   Establishment Registration: 1529041

5. **DATE OF SUBMISSION:** August 11, 2000

6. **DEVICE DESCRIPTION:** The Array Shoulder coil is a receive only two channel coil which can be used in the OPART™ imaging system in Array mode to image the shoulder region and related anatomy. The coil design consists of combining two orthogonal (oriented at 90 degrees with respect to each other) loops which deviate from ideal geometries in order to fit the patient anatomy. This orthogonality is needed to prevent coupling and therefore the two loops act independently.

   For Array mode the NMR signals from the two independent loops are amplified and sent to two separate receivers where they are then combined to provide a resultant image.

7. **SAFETY PARAMETERS:**

Maximum static field strength:	0.35 Tesla
Rate of change of magnetic field:	19T/second
Maximum radio frequency power deposition (SAR):	<1.5 Watt/kg
Acoustic noise levels (maximum):	98.4 dB (A)

8. **IMAGING PERFORMANCE PARAMETERS:**

Specification volume:	Head:	10cm dsv
	Body:	20cm dsv

Sample clinical images are presented for the Array Shoulder coil (Appendix G).

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9. **INTENDED USE**
Diagnostic imaging of anatomy in the shoulder region.

10. **EQUIVALENCY INFORMATION:**
Toshiba America MRI, Inc., believes that the Array Shoulder Coil option for OPART™ system is substantially equivalent to the Mark 5000 Phased Array Shoulder Coil (K983143). The Array Shoulder Coil is manufactured by USA Instruments, Inc. and is a modified version of USA Instruments Mark 5000 Phased Array Shoulder Coil.

The Array Shoulder Coil is identical to the Mark 5000 Phased Array Shoulder Coil (K983143) with some minor modifications added to allow for use with the OPART™ system. Modifications included adjusting the coil's tune frequency to match that of the OPART™ system. Additionally, the Mark 5000 Phased Array Shoulder Coil was modified from a variable tune and fixed match coil to a variable tune and variable match for the Array Shoulder coil. The modifications added to the coil do not raise new questions of safety or efficacy.

This optional coil does not introduce any new indications for use from those cleared in the most recent software Premarket Notification for OPART™ diagnostic resonance system (v3.0/v3.1/v3.2/v3.3) 510(k) number K993574. A comparison table to the predicate device is located in Appendix B.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 5 2000

Bruce Clark
Quality Engineer
Toshiba America MRI, Inc.
280 Utah Avenue
South San Francisco, CA 94080

Re: K002522
OPART™ (Model MRT-600) QD/Array Shoulder Coil
Dated: August 11, 2000
Received: August 15, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 MOS

Dear Mr. Clark:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002522

Device Name: Array Shoulder Coil option for OPART™ (MRT-600)

Indications for Use:

Imaging of:

Diagnostic imaging of anatomy shoulder region.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR§801.109)

David A. Seguin
(Division Sign-Off) (Optional Format 1-2-96)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002522